Michigan Office of Administrative Hearings and Rules Administrative Rules Division (ARD)

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REGULATORY IMPACT STATEMENT and COST-BENEFT ANALYSIS (RIS)

Agency Information:

Department name:

Licensing and Regulatory Affairs

Bureau name:

Marihuana Regulatory Agency

Name of person filling out RIS:

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Rule Set Information:

ARD assigned rule set number:

2019-71 LR

Title of proposed rule set:

Marihuana Infused Products and Edible Marihuana Product

Comparison of Rule(s) to Federal/State/Association Standared:

1. Compare the proposed rules to parallel federal rules or standards set by a state or national licensing agency or accreditation association, if any exist.

There are no federal rules or standards for the regulation of marihuana. There are no other state or national licensing agency standards or accreditation standards for marihuana.

A. Are these rules required by state law or federal mandate?

These rules are required by the Medical Marihuana Facilities Licensing Act and the Michigan Regulation and Taxation of Marihuana Act. There is no federal mandate for these rules.

B. If these rules exceed a federal standard, please identify the federal standard or citation, describe why it is necessary that the proposed rules exceed the federal standard or law, and specify the costs and benefits arising out of the deviation.

These rules do not exceed any federal standards or laws. There are no federal standards or laws in place.

2. Compare the proposed rules to standards in similarly situated states, based on geographic location, topography, natural resources, commonalities, or economic similarities.

Michigan's licensing and regulatory framework is similar to programs in other Great Lakes and surrounding states. Michigan has one of the country's largest patient populations registered with its medical marihuana program, which will presumptively create the consumer base for marihuana businesses. The other states have a tenth of the patient population that Michigan has. The tax in Michigan is 3% of gross receipts of provisioning centers. The tax in Illinois is 7% at cultivators/dispensaries. Pennsylvania has a 5% excise tax on gross receipts of dispensaries. Minnesota has a \$3.50 tax on each gram. Ohio does not have an excise tax on medical marihuana. While there may be neighboring states with higher taxes, the patient population market is far less than that of Michigan. The other programs also have similar licensing categories; however, Michigan is unique with a transporter license available. The only other Great Lakes state that allows recreational/adult-use marijuana is Illinois. Illinois Cannabis Regulation and Tax Act (ICRTA) passed on May 31, 2019, and is effective January 1, 2020. The Illinois Cannabis Regulation and Tax Act is comparable to the MRTMA in that it creates personal possession limits and allows for individuals to cultivate a specific number of plants for themselves. The ICRTA also creates comparable license types to MRTMA.

The proposed rules are consistent with the rules of those states where medical and adult-use marihuana is regulated.

A. If the rules exceed standards in those states, please explain why and specify the costs and benefits arising out of the deviation.

The rules do not exceed the scope of licensing requirements of other states where licensure is required.

3. Identify any laws, rules, and other legal requirements that may duplicate, overlap, or conflict with the proposed rules.

These rules are replacing R333.261, R333.262, and Adult-Use Marihuana Establishments Emergency Rules 45 and 46

A. Explain how the rules have been coordinated, to the extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter. This section should include a discussion of the efforts undertaken by the agency to avoid or minimize duplication.

There are no federal laws applicable to the same activity or subject matter. These proposed rules encompass both the existing emergency rules and the Medical Marihuana Facilities permanent rules into one rule set and replace those two sets. These rules remain working in conjunction with the Michigan Medical Marihuana rules.

4. If MCL 24.232(8) applies and the proposed rules are more stringent than the applicable federally mandated standard, a statement of specific facts that establish the clear and convincing need to adopt the more stringent rules and an explanation of the exceptional circumstances that necessitate the more stringent standards is required.

MCL 24.232(8) does not apply, there is no applicable federally mandated standard.

5. If MCL 24.232(9) applies and the proposed rules are more stringent than the applicable federal standard, either the statute that specifically authorizes the more stringent rules or a statement of the specific facts that establish the clear and convincing need to adopt the more stringent rules and an explanation of the exceptional circumstances that necessitate the more stringent standards is required.

MCL 24.232(9) does not apply, there is no applicable federal standard.

6. Identify the behavior and frequency of behavior that the proposed rules are designed to alter.

The rules are designed to create greater consistency in the production, handling, and labeling of marihuana product and to create cohesion between these practices in both medical and adult-use marihuana businesses. These tests take place on a daily basis. The rules are also intended to create clear and consistent standards for marihuana product.

A. Estimate the change in the frequency of the targeted behavior expected from the proposed rules.

The rules should change or create more consistency in the production, handling, and labeling of marihuana product. This consistency will affect matters daily.

B. Describe the difference between current behavior/practice and desired behavior/practice.

Under the current separate rules, there are differences in the production, handling, and labeling requirements between medical marihuana and adult use marihuana. These rules create consistent practices and update the standards required.

C. What is the desired outcome?

The desired outcome is to protect the public health, safety, and welfare of marihuana users, both medical marihuana patients, and adult-use consumers by ensuring that product is produced, handled, and labeled according to the most current good manufacturing practices.

7. Identify the harm resulting from the behavior that the proposed rules are designed to alter and the likelihood that the harm will occur in the absence of the rule.

The harm that will result is that marihuana product will not be produced, handled, or labeled consistently and will not be produced to the current standards of good manufacturing practices. This could impact the health, safety, and welfare of marihuana product consumers.

A. What is the rationale for changing the rules instead of leaving them as currently written?

The rationale for changing these rules it to create greater consistency in the production and labeling of marihuana product and to ensure that handling and packaging standards are updated to current standards. This cannot be done with the rules as currently written.

8. Describe how the proposed rules protect the health, safety, and welfare of Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply.

The proposed rules create consistent requirements for infused and edible marihuana product that will be available to medical marihuana patients as well as adult-use consumers. They are structured to ensure that marihuana product that is produced is done so according to good manufacturing practices, handled safely, and labeled appropriately for all users.

9. Describe any rules in the affected rule set that are obsolete or unnecessary and can be rescinded.

These rules are replacing R333.261, R333.262, and Adult-Use Marihuana Establishments Emergency Rules 45 and 46.

10. Please provide the fiscal impact on the agency (an estimate of the cost of rule imposition or potential savings for the agency promulgating the rule).

There will be no fiscal impact on the agency. The agency already manages both medical marihuana facilities licensing and adult-use marihuana licensing.

11. Describe whether or not an agency appropriation has been made or a funding source provided for any expenditures associated with the proposed rules.

No appropriations have been made to any governmental units because of these rules. No additional expenditures are anticipated or intended with the proposed rules.

12. Describe how the proposed rules are necessary and suitable to accomplish their purpose, in relationship to the burden(s) the rules place on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts.

The rules must ensure the safety, security, and integrity of the operation of marihuana businesses. Any burdens would be in place as required by the MMFLA, MTA, and MRTMA. The application/licensing process requires documentation, fingerprinting, etc. That will be at a financial and administrative cost. There are rules required for the use of a statewide monitoring system which will place a burden on the individual but is statutorily required. These items are already in place so there will be no increased burden.

A. Despite the identified burden(s), identify how the requirements in the rules are still needed and reasonable compared to the burdens.

The rules must ensure the safety, security, and integrity of the operation of marihuana facilities. Any burden is reasonable in the proposed rules as it complies with the statutory requirement for its consideration.

13. Estimate any increase or decrease in revenues to other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Estimate the cost increases or reductions for other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

There are no anticipated increases or decreases in revenues or costs to other state or local government units as a result of the proposed rules. Any local or state change to revenue may occur via the statutory provisions as it concerns how the funds, fees, or taxes are allocated or expended. The agency is required to set an application fee pursuant to the MMFLA and MRTMA and has set the fee at \$6,000 to offset the background investigations, administration of the licensing application, etc. The other statutorily imposed fee is the annual regulatory assessment/renewal fee set forth in the MMFLA and MRTMA which will be deposited in the marihuana regulatory fund.

14. Discuss any program, service, duty, or responsibility imposed upon any city, county, town, village, or school district by the rules.

These rules do not impose any duties/responsibilities on cities, counties, towns, villages, or school districts, other than the current duties to adopt ordinances to opt-in to allow medical marihuana facilities if they choose, or to opt out of adult-use marihuana establishments if they choose.

A. Describe any actions that governmental units must take to be in compliance with the rules. This section should include items such as record keeping and reporting requirements or changing operational practices.

There are no anticipated actions that a governmental unit must take to comply with these proposed rules.

15. Describe whether or not an appropriation to state or local governmental units has been made or a funding source provided for any additional expenditures associated with the proposed rules.

No appropriations have been made to any governmental units because of these rules. No additional expenditures are anticipated or intended with the proposed rules.

16. In general, what impact will the rules have on rural areas?

The proposed rules are not expected to impact rural areas in as much as the rules apply to all marihuana businesses regardless of location.

A. Describe the types of public or private interests in rural areas that will be affected by the rules.

The proposed rules are not expected to affect public or private interests in rural areas.

17. Do the proposed rules have any impact on the environment? If yes, please explain.

These proposed rules do not have any impact on the environment. These rules contain standards that are in line with requirements of the Department of Environment, Great Lakes, and Energy (EGLE). These rules include EGLE requirements for management of waste, including marihuana waste. The rules indicate that waste must be disposed of in compliance with the National Resources and Environmental Protection Act (NREPA).

18. Describe whether and how the agency considered exempting small businesses from the proposed rules.

The proposed rules are designed to regulate all commercial marihuana businesses, regardless of their size. They are intended to allow any business, including a small business, to obtain a license in the industry.

19. If small businesses are not exempt, describe (a) the manner in which the agency reduced the economic impact of the proposed rules on small businesses, including a detailed recitation of the efforts of the agency to comply with the mandate to reduce the disproportionate impact of the rules upon small businesses as described below (in accordance with MCL 24.240(1)(a-d)), or (b) the reasons such a reduction was not lawful or feasible.

In these rules the application fees are set in a tiered fashion as to make licenses more available for small businesses. The license types available are available to small businesses. These rules, however, are intended to broadly lay out the criteria for a marihuana business to obtain a license. They do not target small businesses, nor do they negatively impact them exclusively.

A. Identify and estimate the number of small businesses affected by the proposed rules and the probable effect on small businesses.

It is uncertain how many small businesses may be affected by the proposed rules. However, the belief is that these proposed rules will make it easier for small businesses to enter into the regulated marihuana market.

B. Describe how the agency established differing compliance or reporting requirements or timetables for small businesses under the rules after projecting the required reporting, record-keeping, and other administrative costs.

The agency did not establish separate compliance or reporting requirements for small businesses.

The proposed rules will apply to all applicants and licensees across the license categories, as applicable. The rules were drafted to be the least burdensome on all applicants and licensees.

C. Describe how the agency consolidated or simplified the compliance and reporting requirements for small businesses and identify the skills necessary to comply with the reporting requirements.

The agency did not consolidate or simplify compliance and reporting requirements for small businesses with the proposed rules.

D. Describe how the agency established performance standards to replace design or operation standards required by the proposed rules.

The agency did not establish performance standards to replace design or operation standards required by these rules.

20. Identify any disproportionate impact the proposed rules may have on small businesses because of their size or geographic location.

The proposed rules affect applicants and/or licensees rather than specifically small businesses. Therefore, there is no disproportionate effect on a small business because of its size or geographic location.

21. Identify the nature of any report and the estimated cost of its preparation by small businesses required to comply with the proposed rules.

There is no report required of small businesses.

22. Analyze the costs of compliance for all small businesses affected by the proposed rules, including costs of equipment, supplies, labor, and increased administrative costs.

There will be no increased costs of compliance for a small business concerning the costs of equipment, supplies, or administrative costs.

23. Identify the nature and estimated cost of any legal, consulting, or accounting services that small businesses would incur in complying with the proposed rules.

Small businesses will not incur any costs of legal, consulting, or accounting services to comply with the rules other than what any marihuana business would incur.

24. Estimate the ability of small businesses to absorb the costs without suffering economic harm and without adversely affecting competition in the marketplace.

There are no expected costs to a small business that will cause economic harm to a small business or the marketplace as a result of the proposed rules.

25. Estimate the cost, if any, to the agency of administering or enforcing a rule that exempts or sets lesser standards for compliance by small businesses.

The proposed rules apply to all applicants and licensees, regardless of size or geographic location. Therefore, exempting or setting lesser compliance standards for small businesses could create a potential threat to health and safety of the state of Michigan.

26. Identify the impact on the public interest of exempting or setting lesser standards of compliance for small businesses.

The proposed rules apply to all applicants and licensees, regardless of size or geographic location. Therefore, exempting or setting lesser compliance standards for small businesses could create a potential threat to health and safety of the state of Michigan.

27. Describe whether and how the agency has involved small businesses in the development of the proposed rules.

The agency worked with the Medical Marihuana Licensing Board (Board) in the development of the proposed rules. Workgroups were also conducted that were comprised with varying levels of business owners, from small or large businesses and members of the public and they made recommendations to the Board. Small businesses were not exclusively included or excluded by the very nature of being a small business.

A. If small businesses were involved in the development of the rules, please identify the business(es).

Small business was involved in the development of rules only in as much as making recommendations during the workgroups to the Board and not specifically to the agency on specifics concerning the proposed rules.

28. Estimate the actual statewide compliance costs of the rule amendments on businesses or groups.

The MMFLA and MRTMA requires that the agency to promulgate rules that ensure the safety, security, and integrity of the operation of marihuana businesses. The statues also require licensees to comply with standards and requirements for marihuana businesses. There are costs associated with the statutory requirements implemented through the proposed rules. This is an existing program, so the actual costs are already in place. These rules will not increase or decrease the compliance costs.

A. Identify the businesses or groups who will be directly affected by, bear the cost of, or directly benefit from the proposed rules.

The rules apply to applicants and licensees. There could be additional businesses or groups affected by, bear the cost of, or directly benefit from the proposed rules. Examples may be CPAs, lab equipment companies, surveillance equipment companies, third-party integrators, and point of sale companies.

B. What additional costs will be imposed on businesses and other groups as a result of these proposed rules (i.e. new equipment, supplies, labor, accounting, or recordkeeping)? Please identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

These proposed rules will not cause the licensees to have to invest in new equipment, supplies, labor, or accounting. Additional recordkeeping will be required for records of formulation for marihuana product intended for inhalation. An additional cost will be incurred for testing marihuana product intended for inhalation.

29. Estimate the actual statewide compliance costs of the proposed rules on individuals (regulated individuals or the public). Include the costs of education, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or recordkeeping.

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There will be license fees set at application for all marihuana business types. An annual regulatory assessment/renewal fee will be imposed as well. The application fee for both an adult-use and medical marihuana facility is the same as it was previously (\$6,000.00). The regulatory fee for adult-use establishments is set by rule and did not change. The annual regulatory assessment under MMFLA is determined by the agency on an annual basis. The current assessments (FY 2020) are as follows:

Grower Class A: \$10,000 (new); \$10,000 (top tier); \$10,000 (middle tier); \$10,000 (bottom tier)

Grower Class B: \$30,000 (new); \$36,000 (top tier); \$30,000 (middle tier); \$24,000 (bottom tier)

Grower Class C: \$56,000 (new); \$67,000 (top tier); \$56,000 (middle tier); \$45,000 (bottom tier)

Processor: \$56,000 (new); \$67,000 (top tier); \$56,000 (middle tier); \$45,000 (bottom tier)

Provisioning Center: \$44,000 (new); \$52,000 (top tier); \$44,000 (middle tier); \$36,000 (bottom tier)

Secure Transporter: \$44,000 (new); \$52,000 (top tier); \$44,000 (middle tier); \$36,000 (bottom tier)

A. How many and what category of individuals will be affected by the rules?

These rules do not change the current licensing fee structure. Applicants for marihuana businesses are required to pay these fees upon licensure and on a yearly basis.

B. What qualitative and quantitative impact do the proposed changes in rules have on these individuals?

This licensed and regulated industry could have an impact on the cost and sale of medical marihuana, and whether someone chooses to become a medical marihuana patient with adult-use marihuana available.

30. Quantify any cost reductions to businesses, individuals, groups of individuals, or governmental units as a result of the proposed rules.

The proposed rules impact applicants and licensees. A cost reduction that could apply is that the application fee could be reduced if the applicant is applying for numerous licenses. (The regulatory assessment will not be reduced however).

- 31. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rules. Please provide both quantitative and qualitative information, as well as your assumptions.
 - a) Establish consistent standards for edible and infused marihuana products across medical and adult-use platforms. This is important in order to protect the integrity of the marihuana industry.
 - b) Establish parity between the adult-use and medical marihuana business, especially so that those holding equivalent licenses are able to operate in a compliant fashion.
- 32. Explain how the proposed rules will impact business growth and job creation (or elimination) in Michigan.

The licensing and regulatory framework that is created will establish a commercial supply and distribution mechanism for marihuana. The license categories create new businesses in the industry that otherwise were not licensed or regulated – and will impact business growth and job creation specifically for those interacting with the licensed marihuana business.

33. Identify any individuals or businesses who will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

The proposed rules specifically focus on the marihuana industrial sector as they implement aspects of the regulatory framework as required by the MMFLA and MRTMA. The operation of these businesses impacts the marihuana customer segment of the public through increased access to marihuana that has been tracked, tested, and labeled to ensure safety for customers. There is no expected disproportionate effect due to business size or geographic location.

34. Identify the sources the agency relied upon in compiling the regulatory impact statement, including the methodology utilized in determining the existence and extent of the impact of the proposed rules and a cost-benefit analysis of the proposed rules.

Sources from other states are the following:

Illinois:

http://www.revenue.state.il.us/QuestionsAndAnswers/139.htm

http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=3503&ChapterID=35

Minnesota:

https://www.revisor.mn.gov/statutes/cite/297D.08

https://www.revisor.mn.gov/laws/?id=311&year=2014&type=0

Ohio:

https://mjbizdaily.com/ohio-mmj-market-could-generate-200m-400m-in-sales/

https://www.medical marijuana.ohio.gov/Documents/advisory-committee/April%202017/Program%20Budget%20-%20Presentation.pdf

https://www.medicalmarijuana.ohio.gov/rules

Pennsylvania:

http://www.revenue.pa.gov/GeneralTaxInformation/Tax%20Types%20and%20Information/Pages/Medical-Marijuana -Tax.aspx#.WUqeBeurrb0

https://www.pa.gov/guides/pennsylvania-medical-marijuana-program/

OTHER:

https://www.leafly.com/news/industry/state-by-state-guide-to-cannabis-advertising-regulations

"House Fiscal Agency and Senate/Department Reports/LAB coalition"

A. How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., which demonstrate a need for the proposed rules.

There were no estimates made because the rules impact an individual licensee or registrant as well as applicant for licensure or registration. No estimate could consider the setting where an individual may use his or her license or registration. Because the rules only impact an individual, and impact all in the same way, the assumptions made was that no additional cost or benefit would result from the proposed rules.

35. Identify any reasonable alternatives to the proposed rules that would achieve the same or similar goals.

The rules are required by the MMFLA and MRTMA; there is no reasonable alternative to the proposed rules.

A. Please include any statutory amendments that may be necessary to achieve such alternatives.

The rulemaking provisions of the MMFLA and MRTMA would have to be removed for any such alternative to occur.

36. Discuss the feasibility of establishing a regulatory program similar to that proposed in the rules that would operate through private market-based mechanisms. Please include a discussion of private market-based systems utilized by other states.

The rules are required by the MMFLA and MRTMA; private market-based systems cannot serve as an alternative.

36. Discuss the feasibility of establishing a regulatory program similar to that proposed in the rules that would operate through private market-based mechanisms. Please include a discussion of private market-based systems utilized by other states.

Since the rules are specifically required by the MMFLA and MRTMA, there are no alternatives to the proposed rules that the agency could consider. They are necessary to ensure the safety, security, and integrity of the operation of marihuana facilities.

38. As required by MCL 24.245b(1)(c), please describe any instructions regarding the method of complying with the rules, if applicable.

There are no additional instructions for complying with the proposed rules.